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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/511,023 | 10/08/2004 | Lars I. E. Oddsson | BU-082XX | 8760 |
| 207 | 7590 | 10/23/2006 | EXAMINER | |
| WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109 | | | SMITH, FANGEMONIQUE A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/511,023 | ODDSSON ET AL. | |
| | Examiner | Art Unit | |
| | Fangemonique Smith | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed August 4, 2006. The Examiner acknowledges the amendment to claims 1, 14-17, 19-39 and 46-66. Please note each claim should be provided with the proper status identifier. Also, claims being currently amended in an amendment paper should be submitted with markings to indicate changes that have been made relative to the immediate prior versions of the claims. Claims 1-70 are pending in the application.

Claim Objections

2. Claims 1, 17 and 66 are objected to because of the following informalities:
- a. At line 4 of claim 1, it is suggested to modify the limitation "said plurality of sensors is" to read -- said plurality of sensors are --.
 - b. At line 6 of claim 17, it is suggested to modify the limitation "said stimulation control signal" to read -- said at least one stimulation control signal --.
 - c. At line 3 of claim 66, it is suggested to modify the limitation "said plurality of sensors is" to read -- said plurality of sensors are --.
- Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 recites the limitation "said sensor" in line 7. Prior to this recitation, the claim recites the limitations "a plurality of sensors" at line 3 and "each sensor within said plurality of sensors" at lines 5 and 6. It is unclear whether this recitation refers to one sensor or to all sensors within the plurality of sensors, rendering the claim indefinite. Upon rejection of claim 1, any claim depending from claim 1 is also rejected.

6. Claims 2-4 recite the limitation "the forces" in line 2. Prior to this recitation, claim 1 recites "a detected magnitude of forces". It is unclear whether this recitation refers to the "detected magnitude of forces" as recited in claim 1 or if the limitation intends to introduce additional forces, rendering the claim indefinite.

7. Claim 14 recites the limitation "said balance information signals" in line 3. Prior to this recitation, claim 1 recites "at least one balance information signal". It is unclear whether the limitation intends to refer to the case of having one or more balance information signals or if the limitation intends to further limit the claim to exclude the event of having one balance information signal, rendering the claim indefinite.

8. Claim 36 recites the limitation "said received stimulation control signal" in lines 2 and 3. There is no prior mention of a received stimulation control signal in claim 36 or in any claim from which claim 37 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

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9. Claims 37, 38, 46, 66 and 67 all recite the limitation "said stimulation control signal".

Prior to the recitation of the limitation in the claims noted above, the limitation "at least one stimulation control signal" is recited. It is unclear whether the limitation in claims 37, 38, 46 and 66-68 intends to refer to only one stimulation control signal or if the limitation intends to refer to one or more stimulation control signal, rendering the claim indefinite. Upon rejection of these claims, any claim depending from the claims above is also rejected.

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 39 recites the broad recitation said at least one stimulation control signal, and the claim also recites said stimulation signal which is the narrower statement of the range/limitation.

11. Claim 58 recites "The method" in line 1. There is no prior mention of a method in claim 58 or in any claim from which claim 58 depends. Therefore there is insufficient antecedent basis for the limitation in the claim.

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12. Claim 65 recites the limitation "the angles" in line 2. It is unclear whether this recitation refers to the angle disclosed by claim 39 or if the limitation intends to introduce additional angles, rendering the claim indefinite.

13. Claim 66 recites the limitation "a plurality of sensors" at line 1 and "said plurality of sensors" in line 6. It is unclear whether either limitation intends to include the at least one sensor disclosed previously in claim 39, or if the claim intends to introduce more sensors, rendering the claim indefinite.

14. Claim 66 recites the limitation "said sensor" in line 6. Prior to this recitation, the claim recites "a plurality of sensors". Additionally, claim 39, a claim from which claim 66 depends, discloses "at least one sensor". It is unclear whether the limitation intends to refer to multiple sensors, at least one sensor or intends to further limit the claim to exclude the event of having more than one sensor, rendering the claim indefinite.

15. Claim 66 recites the limitation "said each of said plurality of sensors" in line 1. It is unclear whether this limitation refers to each sensor within the plurality of sensors, or if it intends to introduce more sets of a plurality of sensors, rendering the claim indefinite.

16. Claims 68-70 each recite the limitation "said stimulation control signals". Prior to the recitation of the limitation in the claims noted above, the limitation "at least one stimulation control signal" is recited. It is unclear whether the limitation in the claims intends to refer to one or more stimulation control signal or intends to exclude the case of having only one stimulation control signal, rendering the claim indefinite.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-4, 14-19, 21-37, 39-41, 46, 47, 49-66 and 68-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Allum (U.S. Patent Number 6,063,046).

In regard to claims 1-4, Allum discloses a method and apparatus for the diagnosis and rehabilitation of balance disorders. The Allum device (20) comprises a plurality of sensors located in the support surface of the device for detecting balance information. The sensors are configured for wearing by placement under at least one foot of the user (col. 4, lines 55-67; col. 5, lines 1-30). The sensors transduce a detected magnitude of forces applied to the sensors and transmit at least one balance information signal to a signal processing subsystem (24). The Allum device further converts the balance information into at least one stimulation control signal. A feedback mechanism acts as a stimulator (38), which is responsive to said at least one stimulation control signal (col. 10, lines 23-42). The stimulator is attachable to a body surface part of the user. The sensors disclosed by Allum are sensitive to forces oriented perpendicular and parallel to said plurality of sensors.

In regard to claims 14-19, 21-37, the signal processing subsystem of the Allum device is further operable to convert the collected balance information signals received from the plurality of sensors into an estimate of a magnitude of force applied to a sole of at least one foot of the user.

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The signal processing system also determines a magnitude of the resultant reaction force applied to a sole of at least one foot of the user. The system incorporates the stimulator signaling means of the device providing a visual, audio, tactile and electro-vestibular feedback to the user upon placing the stimulator signaling means proximate with at least one sensory neuron of said user (col. 10, lines 23-42). Allum discloses the device having at least one stimulator securable to a leg of the user (col. 10, lines 23-67; col. 11-12; col. 13, lines 1-32). Stimulators of the Allum device are also capable of being secured on the head of the user or implantable within the body of the user (col. 26, lines 54-67; col. 27, lines 1-35). The stimulators of the Allum system are responsive to received stimulation control signals and the stimulus amplitudes, frequencies, and locations are indicative of at least one parameter describing forces applied to a sole of said at least one foot (col. 3, lines 5-67; col. 4; col. 5, lines 1-30).

In regard to claims 39-41, 46, 47, 49-66 and 68-70, Allum discloses at least one sensor for transducing an angle between at least one foot and an ipsilateral lower leg of a user. The balance information gathered by the device is transmitted to a signal processing system for converting the balance information into at least one stimulation control signal. A feedback mechanism acts as a stimulator (38), which is responsive to said at least one stimulation control signal (col. 10, lines 23-42). The stimulator is attachable to a body surface part of the user. The sensors disclosed by Allum are operable to determine angles between the foot of the user and the ipsilateral lower leg of the user projected on a coronal or sagittal plane. The signal processing system of the Allum device determines a magnitude of an angle between at least one foot and the ipsilateral leg of the user. The system incorporates the stimulator signaling means of the device providing a visual, audio, tactile and electro-vestibular feedback to the user upon placing the stimulator signaling

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means proximate with at least one sensory neuron of said user (col. 10, lines 23-42). Allum discloses the device having at least one stimulator removably affixed to a leg of the user (col. 10, lines 23-67; col. 11-12; col. 13, lines 1-32). Stimulators of the Allum device are also capable of being secured on the head, arm or trunk of the user, or implantable within the body of the user (col. 26, lines 54-67; col. 27, lines 1-35). The stimulation control signals of the Allum device further encode time derivatives of the magnitude of pressure and of the radial position and angular position of the center of pressure under the foot of the user (col. 5, lines 2-67; col. 15, lines 4-67; col. 16; col. 17, lines 1-40).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 5-10, 20, 42-45 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allum (U.S. Patent Number 6,174,294) in view of Crabb et al. (U.S. Patent Number 6,174,294).

In regard to claims 5-10, 20, 42-45 and 48, Allum discloses the features of the Applicant's invention as described above. Allum does not disclose the sensors being insertable into another device other than the platform. Crabb et al. disclose a limb load monitor, which provides feedback to a patient or user when a preselected force load is met or exceeded on the foot of the user. The plurality of sensors of the Crabb et al. device can be attached to a shoe or a stocking of

a user. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a method and apparatus for the diagnosis and rehabilitation of balance disorders, similar to that disclosed by Allum, to include at least one sensor which can be attached to a shoe or a stocking of a user, similar to that disclosed by Crabb et al., to provide a mechanism which potentially improves the connection between the sensors and the user while increasing the utility of the device.

21. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allum (U.S. Patent Number 6,174,294) in view of Andrews (U.S. Patent Application Publication Number 2002/0055779).

In regard to claims 11-13, Allum discloses the features of the Applicant's invention as described above. Although Allum discloses implantable sensors, Allum does not disclose the sensors within the platform, which comprise the plurality of sensor as implantable within the body of the user. Andrews discloses a neural prosthesis with a sensor having output representative of human body activity. The device disclosed by Andrews performs a body movement analysis according to the data provided by the implantable sensor. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a, similar to that disclosed by Allum, to make the plurality of sensors implantable, similar to that disclosed by Andrews, to provide a discrete analysis system while maintaining the functionality of the device.

22. Claim 38 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allum (U.S. Patent Number 6,063,046) in view of Confer (U.S. Patent Number 4,745,930).

In regard to claims 38 and 67, Allum discloses the features of the Applicant's invention as described above. Allum does not disclose the use of a sensor to determine angle information

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between the upper and lower leg of the user, upon analysis of the data collected. Confer discloses a force sensing insole adapted to be used in association with an electro-goniometer for analyzing gait of a patient. The information gathered by the Confer device includes information regarding the knee angle during gait analysis. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify an apparatus for diagnosis of balance disorders, similar to that disclosed by Allum, to include an electro-goniometer system, similar to that disclosed by Confer, to provide additional motion information for determining forces exerted at the knee of the user.

Response to Arguments

23. In response Applicant's arguments with respect to the Crabb et al. reference, Applicant argues the Crabb et al. reference does not teach having a balance information signal, a stimulation control signal and at least one stimulator. The Examiner respectfully disagrees. The Crabb et al. device uses a plurality of sensors to detect the magnitude of forces applied to the foot of the user to gather information needed for determining when the preset load has been exceeded. Upon exceeding a set threshold, the Crabb et al. device triggers a visual, auditory or vibratory stimulation signal to inform the user of the event of interest. An event of interest may include exceeding a balance range for a user. Examiner submits the Crabb et al. device is fully capable of gathering balance information and processing the signals obtained to trigger a stimulus upon exceeding a balance range threshold as claimed by the Applicant. Examiner acknowledges the claims as amended establish distinguishable differences to overcome the 102(b) rejection of the Office Action dated April 6, 2006 with respect to the Crabb et al.

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reference. However, Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

24. Applicant's arguments with respect to claims 11-13, 21, 22, 37, 38 and 68-70 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

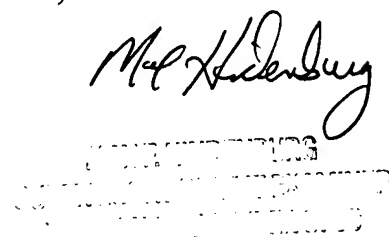
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FS

A handwritten signature in black ink, appearing to read "M. H. Denbury", is written over a faint, rectangular, light-colored stamp. The stamp contains some illegible text and a date that appears to be "JUN 10 2003".